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(54) **Nutritional composition.**

(57) A nutritional composition comprising a combination of specific protein-free carbohydrate and specific protein-free polyunsaturated fat, one of the preferred compositions being the one wherein the protein-free carbohydrate amounts to from 70% to 95% by weight and the protein-free highly polyunsaturated vegetable fat amounts to from 5% to 30% by weight.

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Human nutrition requires a source of the components of protein, carbohydrates, lipids, vitamins and minerals. Many and varied sources for these nutrient materials have been utilized in the prior art. The prior art does not disclose the concept of providing a balanced supply of nutrients which permits substantially complete absorption of the nutrients which are administered to an individual.

Proteins are associated with all forms of life, an observation that dates back to the original identification of protein as a class by Mulder in 1838. The proteins of living matter act as organic catalysts (enzymes), as structural features of the cell, as messengers (peptide hormones), and as antibodies. The importance of protein in the diet is primarily to act as a source of amino acids, some of which are essential (indispensable) dietary constituents because their carbon skeletons are not synthesized in the bodies of animals. It is known that the adult human requires eight amino acids which are essential for the maintenance of good health. These amino acids are isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan and valine.

Amino acid solutions are commercially available for nutrient I.V. feeding of post operative patients, pediatric patients, patients with renal failure and patients with hepatic failure. The available amino acid I.V. solutions are based on crystalline amino acids which have an advantage over the amino acids solutions which were obtained by hydrolysis of proteins such as fibrin or casein. These solutions were nutritionally incomplete in the amino acid content and caused toxic reactions which led to the banning of these solutions in the United States by the Food and Drug Administration.

Amino acid solutions are available which contain all of the essential amino acids in combination with non-essential amino acids, with or without vitamins, minerals and a carbohydrate and fat source.

To estimate the nutritional value of protein as well as amino acid formulas, the accepted methodology is to determine, during the ingestion of a protein(s) or an amino acid formula, the subject's nitrogen balance. This represents the difference between nitrogen intake and nitrogen output, the difference being either positive (nitrogen retention, as in active growth), negative (nitrogen loss), or zero (nitrogen equilibrium).

In order to carefully determine nitrogen balance (nitrogen intake - nitrogen output), I have used the formula: (Munro, H N., Crim M.C., in "Modern Nutrition In Health and Disease" Shils, M.E., Young, V.R. (Eds), page, 24, Lea & Febiger, Philadelphia 1988):

$$B = I - (U + F + S)$$

where:

- B = Nitrogen Balance
- I - Nitrogen Intake
- U = Nitrogen loss In Urine
- F = Nitrogen loss In Feces
- S = Nitrogen Dermal Losses

This formula has been used to compute the Net Nitrogen Utilization (NNU) for the amino acid formulas and proteins that were tested.

The prior art amino acid solutions, which have widely different ratios of the component amino acids, have not been found to be suitable as total nutrient compositions because after prolonged reliance on these compositions, symptoms of nutrient deficiency are detected due to the low percentage of their net nitrogen utilization (NNU). The low net nitrogen utilization (NNU) results in the presence of unabsorbed amino acids, which are deaminated and cause an increased production of blood urea nitrogen (BUN) as well as increased levels of other metabolic nitrogen containing products. This problem is particularly difficult with patients who have renal failure and/or hepatic disorders.

United States Letters Patent No. 3,697,287 disclose an amino acid food composition which is described as a palatable mixture of the essential and non-essential amino acids, minerals, vitamins, carbohydrates and fats. That composition contains essential and non-essential amino acids. The essential amino acids in such a composition are present in the following ratios:

L-valine	1.0
L-arginine	1.77
L-isoleucine	.91
L-lysine	1.03
L-phenylalanine	1.03
L-hystidine	.44
L-leucine	1.43
L-methionine	.93
L-threonine	.91
L-tryptophan	.28

I have discovered that the use of an amino acid composition which contains specific proportions of the essential amino acids will make possibile a higher NNU as compared to high NNU protein such as hen whole egg protein or other amino acid compositions. I have discovered that the oral administration of a composition which consists of essential amino acids will result in a higher NNU as compared to compositions which also include non-essential amino acids. In addition, the use of a preferred embodiment of the invention, will avoid causing or unduly exacerbating the BUN of patients in which the nitrogen intake is required to be restricted who are fed with certain of the applicant's composition. The avoidance of exogenous residual nitrogen is achieved by the formulation of the amino acid composition with a specific ratio of the essential amino acids which provide for substantially complete absorption of the required quantity of the amino acids. The novel amino acid composition of the invention may be utilized alone or in combination with carbohydrates, lipids, vitamins and minerals depending on the particular nutrient requirements of a particular patient.

I have also discovered that the feeding of the amino acid composition of the invention has a profound immunostimulant effect which can be determined by the means of objective clinical criteria.

The main function of dietary carbohydrate is to provide energy. Administration of carbohydrate has long been known to spare protein in early fasting.

Protein is abruptly lost upon initiating a fast or upon withdrawing carbohydrates from an adequate diet (even if replaced isoenergetically by fat). Glucose is the main carbohydrate in the body and although glucose can be utilized by all cells, it is essential only in a few organs, including the brain and the red cells. Although glucose can be converted to fat, it should be noted that fat cannot be converted to glucose. All the dietary carbohydrates seem to reduce the level of high-density lipoprotein (HDL) cholesterol in the serum, and HDL cholesterol: total cholesterol ratio in the serum is reduced to a greater extent by sucrose than by glucose. The type of dietary carbohydrate can alter the level of triglyceridemia, and this effect can be negated by the addition of polyunsaturated fat to the diet.

Dietary lipids consist mainly of triglycerides (TG), a useful and concentrated source of energy. An adequate TG supply and absorption are especially important for infants and also for adults with a high energy requirement, such as patients with major burns, malignant tumors, and surgical wounds. The alternative energy sources, protein and carbohydrates, deliver per gram, 4 Kcal, less than half the energy density of fats, and require bulky meals to cover high energy requirements. Essential Fatty Acids (EFA) are necessary for the normal function of all tissues, it is therefore not surprising that the list of symptoms of EFA deficiency is a long one. As no animal, including man, can synthesize EFA, it is completely dependent on vegetable lipids to meet EFA requirements.

It has been demonstrated convincingly that diets enriched in EFA such as linoleic acid and reduced in saturated fatty acids do lower significantly LDL and VLDL cholesterol in man at both 30 and 40 in % of fat levels (3).

I have discovered that the oral administration of a composition which contains specific proportion of protein-free carbohydrate and protein-free polyunsaturated vegetable fat results in a palatable mixture having the highest apparent digestibility (AD) a higher Energy Density per weight and per volume and a higher content in EFA joined with a lower content in saturated fatty acids of any natural food or palatable dietetic composition for use as a complement in feeding patients such as infants, alcoholics, drug abusers, Acquired Immune Deficiency Syndrome (AIDS) patients, Aids Related Complex (ARC) patients, cancer patients, psychiatric patients, geriatric patients and the like, who have an increased catabolism, and/or fail to eat, because of a physiological and/or psychological lack of appetite.

Each dietary fuel differs in apparent digestibility (%), which is calculated as:

$$\frac{(\text{Intake} - \text{Stool losses}}{\text{Intake}} \times 100$$

To illustrate: If 100 grams of fat are ingested per day, and if the daily stool fat averages 5 grams, then the "apparent digestibility" (AD) of fat is 95%.

I have discovered that the oral administration of a composition which contains specific proportion of mineral-free, protein-free carbohydrate(s) and highly polyunsatyrated vegetable fat(s) with the highest content in EFA join with the lowest content in saturated fatty acids, results in a palatable mixture which will avoid causing or unduly exacerbating the level of High-Density Lipoprotein (HDL) , Low-density-Lipoprotein (LDL) and Very Low-Density-Lipoprotein (VLDL) cholesterol in the serum of patients in which HDL, LDL and VLDL cholesterol level is required to be restricted who are fed with certain of the applicant's composition.

I have also discovered that the oral administration of a composition which contains specific proportion of mineral free, protein-free carbohydrate and highly polyunsaturated vegetable fat results in a palatable mixture which will avoid causing or unduly exacerbating the Blood Urea Nitrogen (BUN) of patients in which nitrogen intake is required to be restricted who are fed with certain of the applicant's compositions.

I have also discovered a novel concept for providing vitamin and mineral requirements by means of a method which is based on the administration of an amount of vitamins and minerals which is proportionate to the amount of amino acid which are administered.

I also discovered an object of the invention to provide an improved palatable mineral free protein-free carbohydrate and highly polyunsaturated vegetable fat based nutrient composition.

It is also an object of the invention to provide a palatable protein-free carbohydrate and protein-free polyunsaturated fat based composition which is useful because of its highest apparent digestibility (AD) and energy density (ED) in the nutritional support of patients suffering from disease where restricted nitrogen intake is indicated such as in certain renal and hepatic dysfunctions.

It is also an object of the invention to provide a palatable mineral-free protein-free carbohydrate and protein-free highly polyunsaturated vegetable fat based composition a higher apparent digestibility (AD) and energy density (ED) content and a higher EFA content joined with a lower saturated fatty acid content of any natural food or palatable dietetic composition for use as a supplement in feeding patients such as infants, alcoholics, drug abusers, Acquired Immune Deficiency Syndrome (AIDS) patients, Aids Related Complex (ARC) patients, cancer patients, psychiatric patients, geriatric patients and the like, who have an increased catabolism, and/or who fail to eat, because of a physiological and/or psychological lack of appetite.

It is also an object of the invention to provide a mineral-free, protein-free carbohydrate and highly polyunsaturated vegetable fat based composition which has the advantage of low storage and shipping cost which may be used as an emergency food to be shippen by air in response to catastrophic events.

SUMMARY OF THE INVENTION

The invention comprises a novel amino acid composition comprising a combination of the following essential amino acids
isoleucine;
leucine;
lysine;
methionine;
phenylalanine;
threonine;
tryptophan; and
valine
in amounts relative to one another which will provide a net nitrogen utilization (NNU) of at least 75%, preferably 80% or 90% and most preferably 95%. The composition may also contain carbohydrates, Essential Fatty Acid (EFA) sources, vitamins and/or minerals.

The amino acid composition has particular use in providing essential nutrients for the prevention or treatment of Protein-Calorie Malnutrition (PCM), in feeding patients such as infants, alcoholics, drug abusers, Acquired Immune Deficiency Syndrome (AIDS) patients, Aids Related Complex (ARC) patients, cancer patients, psychiatric patients, geriatric patients and the like, who have an increased catabolism and/or who fail to eat, because of a physiological and/or psychological lack of appetite.

In particular, the amino acid composition may also be used for supportive nutrition in the case of trauma due to burns, surgery or in diseases, such as kidney disorders, liver disorders, hypercholesterolemia, diabetes mellitus, gout, and the like. A specific application is in the treatment and prevention of obesity which has been successfully treated with certain preferred compositions of the invention.

The invention also comprises a novel palatable nutritional composition comprising a combination of a specific protein-free carbohydrate and specific protein-free polyunsaturated fat: protein-free carbohydrate 70-95 wt.% protein-free highly polyunsaturated vegetable fat 5-30 wt.%

These specific carbohydrate and specific polyunsaturated fat compositions may be used alone or in combination with the amino acid composition of the invention in amounts that vary according to the nutritional requirements of the patient. This may vary between 12 Kcal to 60 Kcal per gram of amino acids.

The preferred ranges are from 80-90 wt.%, protein-free carbohydrate and 20-10 wt.% highly polysaturated vegetable fat and the especially preferred ranges are respectively about 85 wt.% to about 15 wt.%.

The composition made by specific mineral-free, protein-free carbohydrate and specific highly polyunsaturated vegetable fat, in amounts relative to one another, will provide a apparent digestibility of at least 75%, preferably 80% and most preferably 95%, and which will provide the highest apparent digestibility

(Heymfield, S.D. , Williams, P.J. in "Modern Nutrition In Health and Disease", Shils, M.E., Young, V.R. (Eds), page 819, Lea & Febiger, Philadelphia 1988)AD and energy density of any natural food or dietetic composition. The mineral-free, protein-free carbohydrate and highly polyunsaturated vegetable fat composition will provide an exceptional high Energy Density, providing in the liquid form composition at least 4 Kcal/cc = 3 Kcal/g, preferably 4.4 Kcal/cc = 3.4 Kcal/g, and high lipids' polyunsaturated/saturated (P/S) ratio, providing a P/S of a least 4.6, preferably 7.0 and most preferably 8.2, compared with any natural food or palatable dietetic composition. The composition may also contain vitamins and/or minerals.

The specific carbohydrate and specific polyunsaturated vegetable fat compositions have particular use in providing energy and Essential Fatty Acids (EFA), for prevention of treatment of Protein-Calorie Malnutrition (PCM). In particular, the composition may be used when further energy and EFA intake is required, and specifically as a complement of amino acid composition intake for supportive nutrition in the case of trauma due to burns, surgery or in disease, such as renal disorders, liver disorders, diabetes mellitus, gout, and the like.

The specific carbohydrate and specific polyunsaturated vegetable fat compositions of the invention may be utilized as a complement, in the prevention and treatment of Protein-Calorie Malnutrition (PCM) as a supplement and/or substitute of carbohydrate and/or fat of the regular diet. In particular, the compositions, may be used as a nutritional complement in conditions such as:

Protein-Calorie Malnutrition (PCM), cystic fibrosis, anorexia nervosa, immunodeficiency caused by malnutrition treatment and prevention of malnutrition in AIDS patients, gout, hepatic disorders, burn therapy, renal disorders, alcoholism rehabilitation, tuberculosis, pre and post surgery, hospitalized patients' diet, neurological disorders patients, cancer patients, chronic diseases, illicit-drug rehabilitation, malabsorption, food allergy, diarrhea, diabetes mellitus, nutrition in infants, nutrition in adolescents, nutrition in adults, nutrition in elderly.

The specific carbohydrate and specific polyunsaturated vegetable fat compositions of the invention are of special utility in providing nutritional complement to pateits suffering from Acquired Immune Deficiency Syndrome (AIDS) or Aids Related Complex (ARC) in the treatment of Protein-Calorie Malnutrition (PCM), such as kwashiorkor or marasmus and the like.

If desired the specific carbohydrate and specific polyunsaturated vegetable fat compositions of the invention may be used as supplement/replacement compositions for use in providing and/or enhancing a basic source of nutrition for infants, children and adults. It is of particular utility in geriatric patients.

The composition may be given as a solution in water, or as a dispersion in a suitable liquid, or semisolid medium.

The specific protein-free carbohydrate and protein-free polyunsaturated fat are those which provide an apparent digestibility (AD) of at least 75%. Using this parameter of evaluation, it is possibile using the compositions and methods of the present invention to obtain at least 90% AD and through the use of preferred embodiments up to 99% AD.

The exceptional high AD and energetic (Energy Density) content, per weight and per volume, are obtained because of the extremely high absorption rates that are possible because of the particular compositions devised by the applicant.

DETAILED DESCRIPTION OF THE INVENTION

The amino acid composition of the invention is based on the use of crystalline amino acids in specific relative amounts which provide an net nitrogen utilization (NNU) of at least 75%. For example, if a particular subject who is fed which an amino acid formula has a nitrogen intake of 100.0 g. and a total nitrogen output of 100.0 g., the NNU of the formula is 100%. If the subject's nitrogen intake is 100 and the output is 128, then the NNU of the formula is 72%.

Using this parameter of evaluation, it is possible using the compositions and methods of the present invention to obtain at least 90% NNU and through the use of preferred embodiments up to 100% NNU.

The exceptionally high NNU are believed to be obtained because of the extremely high absorption rates that are possible because of the particular compositions devised by the applicant.

The amino acid composition of the invention comprise those having the following proportions of amino acids in grams per 10 grams of composition:

(a) from 1.217 to 1.647 isoleucine;
(b) from 1.827 to 2.735 leucine;
(c) from 1.260 to 2.359 lysine;
(d) from 0.232 to 0.778 methionine;
(e) from 0.843 to 1.314 phenylalanine;
(f) from 0.970 to 1.287 threonine;
(g) from 0.208 to 0.467 tryptophan;
(h) from 1.260 to 1.900 valine.

		(I)	
isoleucine	1.217	-	1.530
leucine	1.827	-	2.735
lysine	1.260	-	2.078
methionine	0.232	-	0.778
phenylalanine	0.934	-	1.314
threonine	0.970	-	1.287
tryptophan	0.208	-	0.467
valine	1.391	-	1.900

		(II)	
isoleucine	1.251	-	1.647
leucine	1.846	-	2.130
lysine	2.023	-	2.359
methionine	0.490	-	0.778
phenylalanine	0.843	-	1.144
threonine	1.053	-	1.287
tryptophan	0.238	-	0.401
valine	1.260	-	1.426

		(III)	
isoleucine	1.289	-	1.647
leucine	1.917	-	2.130
lysine	2.023	-	2.359
methionine	0.490	-	0.778
phenylalanine	0.843	-	1.144
threonine	1.053	-	1.271
tryptophan	0.238	-	0.319
valine	1.342	-	1.426

		(IV)	
isoleucine	1.251	-	1.408
leucine	1.846	-	2.054
lysine	2.086	-	2.359
methionine	0.621	-	0.778
phenylalanine	0.969	-	1.144
threonine	1.106	-	1.287
tryptophan	0.293	-	0.401
valine	1.260	-	1.422

		(V)	
isoleucine	1.372	-	1.530
leucine	1.827	-	2.539
lysine	1.550	-	2.078
methionine	0.490	-	0.708
phenylalanine	0.969	-	1.177
threonine	0.970	-	1.157
trypthophan	0.208	-	0.373
valine	1.422	-	1.600

		(VI)	
isoleucine	1.217	-	1.530
leucine	1.952	-	2.735
lysine	1.260	-	1.999
methionine	0.232	-	0.778
phenylalanine	0.934	-	1.314
threonine	1.043	-	1.287
tryptophan	0.266	-	0.467
valine	1.391	-	1.900

		(VII)	
isoleucine	1.372	-	1.445
leucine	2.192	-	2.539
lysine	1.550	-	1.770
methionine	0.490	-	0.642
phenylalanine	0.969	-	1.155
threonine	0.970	-	1.052
tryptophan	0.282	-	0.319
valine	1.486	-	1.571

		(VIII)	
isoleucine	1.451	-	1.530
leucine	1.827	-	1.846
lysine	2.020	-	2.078
methionine	0.490	-	0.642
phenylalanine	0.969	-	1.144
threonine	1.115	-	1.157
trypthophan	0.368	-	0.373
valine	1.422	-	1.483

		(IX)	
isoleucine	1.328	-	1.357
leucine	1.917	-	1.951
lysine	2.086	-	2.250
methionine	0.642	-	0.673
phenylalanine	0.969	-	1.144
threonine	1.196	-	1.287
tryptophan	0.333	-	0.340
valine	1.342	-	1.422

		(X)	
isoleucine	1.366	-	1.408
leucine	1.846	-	1.917
lysine	2.267	-	2.359
methionine	0.674	-	0.778
phenylalanine	0.969	-	1.144
threonine	1.106	-	1.157
trypthophan	0.311	-	0.333
valine	1.260	-	1.313

		(XI)	
isoleucine	1.289	-	1.647
leucine	1.917	-	2.130
lysine	2.023	-	2.359
methionine	0.622	-	0.778
phenylalanine	0.843	-	0.988
threonine	1.053	-	1.271
tryptophan	0.238	-	0.298
valine	1.342	-	1.426

		(XII)	
isoleucine	1.251	-	1.328
leucine	1.950	-	2.067
lysine	2.078	-	2.315
methionine	0.490	-	0.689
phenylalanine	0.969	-	1.144
threonine	1.106	-	1.152
tryptophan	0.282	-	0.401
valine	1.306	-	1.422

Preferred compositions include the following proportions by weight of the amino acids:

		(XIII)	
isoleucine	1.217	-	1.477
leucine	2.281	-	2.735
lysine	1.332	-	1.999
methyonine	0.232	-	0.608
phenylalanine	0.934	-	1.136
threonine	1.043	-	1.287
tryptophan	0.304	-	0.467
valine	1.391	-	1.900

		(XIV)	
isoleucine	1.408	-	1.530
leucine	1.952	-	2.077
lysine	1.260	-	1.521
methionine	0.674	-	0.778
phenylalanine	1.257	-	1.314
threonine	1.106	-	1.146
tryptophan	0.266	-	0.373
valine	1.581	-	1.700

The especially preferred compositions include those having the following proportions by weight:

	(I)	(II)
isoleucine	1.438	1.482
leucine	2.287	1.963
lysine	1.650	1.428
methionine	0.283	0.699
phenylalanine	0.943	1.288
threonine	1.226	1.111
tryptophan	0.448	0.368
valine	1.721	1.656

	(III)	(IV)
isoleucine	1.310	1.341
leucine	2.053	1.922
lysine	2.189	2.144
methionine	0.621	0.651
phenylalanine	1.029	1.027
threonine	1.107	1.211
tryptophan	0.293	0.338
valine	1.390	1.358

	(V)	(VI)
isoleucine	1.381	1.311
leucine	1.891	1.951
lysine	2.297	2.266
methionine	0.682	0.752
phenylalanine	1.029	0.959
threonine	1.113	1.119
tryptophan	0.318	0.256
valine	1.284	1.376

	(VII)	(VIII)
isoleucine	1.443	1.488
luecine	2.226	1.832
lysine	1.760	2.064
methionine	0.556	0.580
phenylalanine	1.100	1.067
threonine	1.041	1.136
tryptophan	0.317	0.371
valine	1.553	1.461

The compositions of the invention may be utilized in the prevention and/or treatment of nutritional and/or metabolic disorders in healthy or sick people as a supplement and/or substitute to the regular diet. In particular, the compositions may be used for nutrition in conditions such as: Protein-Calorie Malnutrition (PCM), cystic fibrosis, anorexia nervosa, immunodeficiency caused by malnutrition, treatment and prevention of malnutrition in AIDS patients, gout, renal failure, hepatic disorders, burn therapy, hypovitaminosis, hypercholesterolemia, hypoalbuminemia, alcoholism, hemophilia, tuberculosis, pre and post-surgery, hospitalized patients' diet, neurologic disorders patients, pre-menstrual edema and nutritional losses of menstruation, neoplasms, chronic diseases, illicit-drug rehabilitation, malabsorption, food allergy, peptic ulcer, diarrhea, gastrointestinal disorders, short bowel syndrome, hyperlipidemia, diabetes mellitus, gall bladder disorders, nutrition in infants, nutrition in adolescents, nutrition in adults, nutrition in elderly, nutrition in convalesent patients and nutrition during athlete's training.

The amino acid composition of the invention is of special utility in providing nutrition to patients suffering from Acquired Immune Deficiency Syndrome (AIDS) or Aids Related Complex (ARC). The composition of the invention may also be used in the treatment of Protein-Calorie Malnutrition (PCM), such as kwashiorkor, marasmus and the like.

If desired, the amino acid composition of the invention may be used to the treatment and prevention of obesity, or as a supplement/replacement composition for use in providing and/or enhancing a basic source of nutrition for infants, children and adults. It is of particular utility in geriatric patients.

In the treatment and prevention of obesity, as well as in the maintenance of optimal body weight it may be desirable to include decreasing amounts of a source of calories to avoid hypoglycemia. For example, in the first day may include 2000 Kcal and this may be decreased by 200 Kcal for each day to a minimum of

800 K/cal/day. For physician supervised diets in an institution, a diet without any substantial source of calories may be used after gradually decreasing amounts of a source of calories are used. The calorie content may be reduced to less than 100 Kcal may be used, if necessary.

It is possible to substitute cysteine for part of the methionine component; and to substitute tyrosine for part of the phenylalanine component.

The amino acid compositions of the invention have particular use in pregnancy because the proper requirement of protein is supplied without increasing Blood Urea Nitrogen (BUN) or other nitrogen metabolic residuals; in addition, its use prevents nutritional and metabolic disorders and their consequences during pregnancy and lactation.

The amount of the amino acid composition to be used in each particular condition may generally be determined by titration of individual patients to obtain the desired nutritional response or by use of from 0.5 g to 5.0 g/kg of ideal body weight/per day of the amino acid composition of the invention, and preferably from 1.0 g to 2.0 g/kg of body ideal weight/per day given orally or parenteraly. Certain of the compositions of the invention may be used intravenously, however, the preferred route of administration is orally via normal feeding or by a stomach tube because adsorption is higher and the nosocomial infections associated with intravenous feeding may be avoided. The amino acid composition may be administered dry as a powder, in capsules or tablets, as a solution or dispersion in a suitable liquid, or in a semi-solid medium. The ideal weight is determined according to the method set forth in Example I.

The mineral-free, protein-free carbohydrate and highly polyunsaturated vegetable fat composition of the invention is based on the use of specific mineral-free, protein-free carbohydrate(s) and mineral-free, protein-free highly polyunsaturated vegetable fat(s), which will provide an exceptional high AD, providing an apparent digestibility of at least 75%, preferably 80% and most preferably 95%.

The use of mineral-free, protein-free carbohydrate(s) is in the form of the alcohol of glucose, namely sorbitol (glucitol), and/or disaccharides, namely sucrose, and/or maltose. Sorbitol has a therapeutic value as a replacement carbohydrate in the diet of diabetics; sucrose is perhaps the most common and best known disaccharide in the diet, and maltose, which has a relative sweetness value of 40, can replace all or part of the sucrose contents to decrease the sweetness of the composition, and make it more palatable.

The use of mineral-free, protein-free vegetable fat is in the form of vegetable oils with a polyunsaturated/saturated ratio (P/S ratio) of at least 4.6, preferably 7.0 and most preferably 8.2. The use of vegetable oils with a very high (more than 4.5 P/S ratio), namely safflower oil (8.2 P/S ratio, and/or sunflower oil (7.0 P/S ratio), and/or corn oil (4.6 P/S ratio) (5), is because has been demonstrated convincingly that diets enriched in EFA such as linoleic acid (highly present in safflower oil and/or sunflower oil and/or corn oil) and reduced in saturated fatty acids do lower significantly LDL and VLDL cholesterol in man at both 30 and 40 in % of fat levels.

It is to be understood that one or more of the mineral-free, protein-free carbihydrates may be used with one or more of the highly polyunsatured vegetable fats to provide a composition having the desired flavor and calorie content. Distilled water or any other suitable mineral-free diluent may be added, as desired.

The exceptional high AD of the nutritional composition of the invention, providing a carbohydrate and vegetable fat composition with an exceptional high apparent digestibility (AD) , providing at least 75%, preferably 80% and most preferably 95% AD, and an exceptional high Energy density, providing in the liquid form composition at least 4Kcal/cc (3Kcal/g), preferably 4.4 Kcal/cc (3.4 Kcal/g), and most preferably 4.7 Kcal/cc (3.7 Kcal/g), and an exceptional vegetable fat P/S ratio, providing a P/S of at least 4.6, preferably 7.0 and most preferably 8.2 are obtained by the use of the applicants' compositions.

Formula I	
Maltose	70-95 wt. %
Safflower Oil	5-30 wt. %
TOTAL	100.0 wt. %

Formula II	
Maltose	70-95 wt. %
Safflower Oil and Sunflower Oil	5-30 wt. %
TOTAL	100.0 wt. %

(The safflower oil and sunflower oil may comprise from 1-99 wt. % to 99-1 wt. % of the total oil content)

Formula III	
Sorbitol	70-95 wt. %
Safflower Oil	5-30 wt. %
TOTAL	100.0 wt. %

Formula IV	
Sorbitol	70-95 wt. %
Safflower Oil and Sunflower Oil	5-30 wt. %
TOTAL	100.0 wt. %

(The safflower oil and sunflower oil may comprise from 1-99% wt. % to 99-1 wt. % of the total oil content)

Formula V	
Sucrose and Maltose	70-95 wt. %
Corn Oil	5-30 wt. %
TOTAL	100.0 wt. %

Formula VI	
Sucrose and Maltose	70-95 wt. %
Sunflower Oil	5-30 wt. %
TOTAL	100.0 wt. %

Formula VII	
Sorbitol and Maltose	70-95 wt. %
Safflower Oil	5-30 wt. %
TOTAL	100.0 wt. %

Formula VIII	
Sorbitol and Maltose	70-95 wt. %
Safflower Oil and Sunflower Oil	5-30 wt. %
TOTAL	100.0 wt. %

(The safflower oil and sunflower oil may comprise from 1-99 wt. % to 99-1 wt. % of the total oil content)

Formula IX	
Sucrose, Maltose and Sorbitol	70-95 wt. %
Safflower Oil, Sunflower Oil and Corn Oil	5-30 wt. %
TOTAL	100.0 wt. %

(The safflower oil, sunflower oil and corn oil may comprise from 1-99 wt. % to 99-1 wt. % of the total oil content)

Formula X	
Sucrose, Maltose and Sorbitol	70-95 wt. %
Corn Oil	5-30 wt. %
TOTAL	100.0 wt. %

Vitamins are organic micronutrients essential for normal growth and maintenance of life. Vitamins cannot be synthesized by the organism and for these reasons they have to be supplied from an exogenous source. Vitamins provide the only source of certain coenzymes necessary for metabolism, the biochemical process that supports life. Vitamins are classified as fat-soluble and water-soluble. Fat-soluble vitamins, namely A, D, E and K are stored in body fat and may therefore accumulate in quantities that can be toxid. The B vitamins and vitamine C are water-soluble and most of them are rapidly excreted in the urine and thus rarely cause toxicity. Vitamin C and B12 tend to be stored in the body.

Effects of vitamin(s) deficiency, as well, as, toxicity (excessive intake) are dangerous to health, and must be avoided.

The inorganic nutritional minerals and trace elements present in food are essential for health. Some such as calcium, phosphorus, and potassium, occur in the body in concentrations 0.005%. Others termed "trace elements" such as iron, zinc, and iodine, occur in much smaller concentrations (0.005%).

The inorganic elements have many functions such as electrolytes, components of the bones and teeth, components of the prosthetic group of enzymes, and others.

Effects of mineral(s) deficiency, as well as, toxicity (excessive intake) are dangerous for health and must be avoided.

The preferred group of vitamins and minerals are set forth below. It should be understood that variations in the preferred group may be made but the essence of the applicant's inventive use of vitamins and minerals in the administration of these nutritional elements is in the use of a specific ratio of vitamins and minerals to the total amount of specific amino acids administered to a particular patient taking into consideration the interrelationship specific amino acid(s), vitamin(s) and mineral(s). This is to allow high NNU, as well as, to avoid hypo or hypervitaminnosis (deficiency or toxicity).

Sodium	13.00 - 23.00 mg
Potassium	41.00 - 69.00 mg
Magnesium	2.50 - 5.00 mg
Calcium	27.00 - 45.00 mg
Manganese	1.50 - 3.50 mcg
Iron	37.00 -100.00 mcg
Cobalt	1.00 - 2.00 mcg
Copper	35.00 - 65.00 mcg
Zinc	0.16 - 0.28 mg
Nickel	0.75 - 2.50 mcg
Chromium	50.00 - 85.00 mcg
Molybdenum	0.70 - 5.00 mcg
Vanadium	0.35 - 0.65 mcg
Phosphorus	11.00 - 35.00 mg
Chloride	30.00 - 50.00 mg
Fluoride	13.00 - 22.00 mcg
Iodine	4.00 - 8.00 mcg
Selenium	2.00 - 4.50 mcg
Bromine	0.07 - 0.13 mg
Boron	4.00 - 8.00 mcg
Silicon	22.00 - 40.00 mg
Vitamin A	60.02 - 109.00 mcg
Vitamin D	37.00 - 63.00 ng
Alpha-Tocopherol	0.78 - 1.30 ng
Vitamin K	2.00 - 4.00 mcg
Vitamin B1	10.00 - 20.00 mcg
Vitamin B2	27.00 - 48.00 mcg

Nicotinamide	0.13 -	0.23 mg
Pantotenic Acid	0.18 -	0.18 mcg
Vitamin B6	13.00 -	23.00 mcg
Biotin	0.43 -	0.73 mcg
Folic Acid	3.50 -	6.50 mcg
Vitamin B12	35.00 -	65.00 ng
Vitamin C	3.00 -	6.50 mg

The compositions of the invention may be given as dry as a powder, or as tablets, or as a solution in water, or as a dispersion in a suitable liquid, or semi-solid medium. The mineral-free, protein-free carbohydrate and highly polyunsaturated vegetable oil compositions of the invention may be utilized as a complement in the prevention and treatment of Protein-Calorie Malnutrition (PCM) or as a supplement and/or substitute of carbohydrate and/or fat of the regular diet. In particular, these compositions may be used for nutritional complement in conditions such as: Protein Calorie Malnutrition (PCM), cystic fibrosis, anorexia nervosa, immunodeficiency caused by malnutrition, treatment and prevention of malnutrition in AIDS patients, hypercholesterolemia, gout, hepatic disorders, burn therapy, renal disorders, alcoholism rehabilitation, tuberculosis, pre and post surgery, hospitalized patients' diet, neurological disorders, cancer patients, chronic diseased, illicit-drug rehabilitation, malabsorption, food allergy, diarrhea, diabetes mellitus, nutrition in infants, nutrition in adolescents, nutrition in adults, nutrition in elderly.

These compositions of the invention are of special utility in providing a nutritional complement to patients suffering from Acquired Immune Deficiency Syndrome (AIDS) or Aids Related Complex (ARC).

The composition of the invention may also be used as a complement in the treatment of Protein-Calorie Malnutrition (PCM), such as kwashiorkor or marasmus and the like.

If desired, the composition of the invention may be used as a supplement/replacement composition for use in providing and/or enhancing a basic source of nutrition for infants, children and adults. It is of particular utility in geriatric patients.

The amount of the composition to be used in each particular condition may generally be determinated in accordance of the energetic need of individual patients to obtain that desired nutritional response. The preferred route is the oral route, but a tube may be used for direct infusion into the alimentary tract.

When patients are treated with compositions according to this invention, it is desirable to initially administer 10% of the total calculated dose and to increase the dose by 10% per day over a 10 day period. This is done to avoid gastrointestinal problems such as bloating and diarrhea.

The composition may be given as a solution in water, or as a dispersion in a suitable liquid, or semisolid medium.

It is to be understood that convention sources of dietary fiber may be taken in combination with the compositions of the invention, if desired. These sources include fruits, poyllium, bran, vegetables, etc.

EXAMPLE I

A comparative double-blind, triple cross-over study was carried out in sixty-six subjects, during a 114 day period, to examine subject's nitrogen balances to determine the net nitrogen utilization (NNU) of consumed protein or amino acid formula, during Diets A, B and C.

A group of 66 patients were fed with a Metabolism Equalizing and Stabilizing Diet (MESD) for a 30 day period. The composition of the formula in grams per 10 grams of amino acids was:

Table I

Ile	1.438
Leu	2.281
Lys	1.650
Met	0.283
Phe	0.943
Thr	1.226
Trp	0.448
Val	1.721

Sixty-six healthy subjects were fed with MESD, during the 30 day period, in the preliminary phase of this study, with the purpose of equalizing and stabilizing their protein and energy metabolisms thus avoiding different metabolism degrees, which could affect their nitrogen balances.

To avoid common errors in energy intake, which also could affect nitrogen balance, MESD supplied a constant energy intake per subject equivalent to 50 Kcal/Kg/day, during the 30 day period.

To avoid common errors in nitrogen intake, which could affect the nitrogen balance, the carbohydrate and fat of MESD were selected from the essentially protein-free foods of Table IA.

Table IA

Food	Composition x 100 g	Energy
Fruits:	Protein	(Calories)
Apricot	0.8	57
Pineapple	0.4	52
Peach	0.8	52
Strawberry	0.8	36
Pondapple	0.4	52
Tangerine	0.7	43
Mango	0.5	59
Apple	0.3	58
Muskmelon	0.5	25
Orange	0.7	50
Loquat	0.2	44
Papaya	0.5	32
Pear	0.3	56
Watermelon	0.5	22
Vegetables:		
Celery	0.8	19
Eggplant	1.0	27
Waxgourd	0.5	14
Chayote	0.9	31
Lettuce	1.0	13
Cucumber	0.7	15

Ripe tomato	0.8	21
Sweet Cassava	1.0	132
Carrot	0.8	41
Sucrose	0.0	384
Corn oil	0.0	384
Maltose	0.0	384
Sorbitol	0.0	384
Sufflower Oil	0.0	884
Sunflower Oil	0.0	884
Corn Oil	0.0	884

To avoid unnecessary nitrogen loss, and to stabilize subjects' protein metabolisms, MESD also supplied a decreasing amount of protein from the amino acid formula (Table I) during the 30 day period as follows:

(a) 1st and 2nd day: protein intake of 0.80 g/Kg/day;
(b) 3rd and 4th day: protein intake of 0.75 g/Kg/day;
(c) 5th and 6th day: protein intake of 0.70 g/Kg/day;
(d) 7th and 8th day: protein intake of 0.65 g/kg/day;
(e) 9th and 10th day: protein intake of 0.60 g/Kg/day;
(f)11th and 12th day: protein intake of 0.55 g/Kg/day;
(g)13th and 14th day: protein intake of 0.50 g/Kg/day;
(h)15th and 16th day: protein intake of 0.45 g/Kg/day; and
(i) from the 17th to the 30th day: protein intake of 0.40 g/Kg/day.

The protein requirement was calculated for each subject in accordance with each subjects ideal weight. The amino acid formula was fed in three divided doses at 8:00 a.m.; 2:00 p.m. and 8:00 p.m. A vitamin-mineral supplement according to Example 4 was also fed to each patient.

After the MESD conclusion, at the beginning of the main phase, the sixty-six healthy subjects were randomly divided into three matched groups, according to sex and number, and named Groups 1, 2 and 3. In accordance with the diet sequence (Table II), the main phase of this study, was conducted during three consecutive 28 day periods, with the purpose of examining subjects' nitrogen balances, in order to evaluate their net nitrogen utilization (NNU) of consumed protein and amino acid formulas, during the periods of Diets A, B and C.

Table II

Sequence of the Diets by Group	
Group 1	MESD----------A----------B----------C
Group 2	MESD----------B----------C----------A
Group 3	MESD----------C----------A----------B

To achieve this purpose, Groups 1, 2 and 3, each comprised of twenty-two healthy subjects, were fed with diets A, B and C, following the obligatory sequence (Table II) and schedule (Table III).

Table III

Sequence of Diets by Group and Period			
	Group 1	Group 2	Group 3
First Period (28 days) Diet	A	B	C
Second Period (28 days) Diet	B	C	A
Third Period (28 days) Diet	C	A	B

Diets A, B, and C consisted of an identical composition of protein, carbohydrate, fat, vitamins and minerals, but of a different protein source. The diets had the following characteristics:

DIET "A" provided to the subject, a protein intake of 0.4 g/Kg/day, equivalent to 64 mg/Kg/day of nitrogen, from the amino acid formula of Table I and an energy intake of 50 Kcal/Kg/day, from protein-free carbohydrate and fat from Table IA.

DIET "B" provided to the subject a protein intake of 40.4 g/Kg/day, equivalent to 64 mg/Kg/day of nitrogen, from hen whole egg amino acid formula (Table IV) and an energy intake of 50 Kcal/Kg/day, from protein-free carbohydrate and fat from Table IA.

Table IV

Amino Acid Composition of Hen Whole Egg (Based on the data present in Orr, M.D. and Watt, B.K., "Amino Acid Content of Foods" U.S. Dept. Agr., 1957.	
(Grams of amino acids in 100 g of protein)	
Arg	1.04
Asp	7.75
Cys-Cys	2.58
Glu	13.69
Gly	3.91
His	2.65
Ile	7.35
Leu	9.73
Lys	7.08
Met	3.46
Phe	6.39
Pro	4.69
Ser	9.29
Thr	5.50
Trp	1.82
Tyr	4.76
Val	8.21

Corn Oil and sucrose were added to the previous composition, in the following amounts, to provide an energy content in the form of fat and carbohydrate content that approximates that of dried hen whole egg. (Based on the data presented in Orr, M.D., and Watt, B.K., "Amino Acid Content of Foods" U.S. Dept. Agr., 1957.

Corn Oil	90.00 g
Sucrose	7.00 g

The achievement of the equalization among formula compositions was obtained by adding to both Diet A - formula of Table I, and Diet B - hen whole egg amino acids formula of Table IV the amount of 0.9 g of fat (corn oil), plus 0.07 g of carbohydrate (sucrose) per each gram of protein content of the formulas, achieving an equivalent composition of protein, fat and carbohydrate as contained in the Diet C - dried hen whole egg as follows:

Dried Hen Whole Egg Composition in 100 g. (INCAP-ICNND Composition of Foods, 1961)	
Protein	47.0 g
Fat	41.2 g
Carbohydrate	3.4 g
Kcal.	584

DIET "C" provided to the subject a protein intake of 0.4 g/kg/day, equivalent to 64 mg/kg/day of nitrogen, from dried hen whole egg and an energy intake of 50 Kcal/kg/day from protein-free carbohydrate and fat (Table IA).

To avoid common errors in determining nitrogen intake, which could affect the nitrogen balance, the carbohydrate and fat of Diets A, B and C were substantially protein-free (Table IA).

To avoid common errors in determining energy intake, which could also affect nitrogen balance, Diets A, B and C supplied a constant energy intake per subject equivalent to 50 Kcal/kg/day, during each 28 day period.

To avoid over-estimating nitrogen intake, caused by unconsumed daily protein or amino acids formula during each 28 day period, all sixty-six subjects were fed three times per day (8:00 a.m.; 2:00 p.m.; and 8:00 p.m.) achieving the total consumption of their allotted formula.

To avoid error in determining energy intake, which could affect nitrogen balance, formulas given during Diets A, B and C had an equivalent composition of protein, fat and carbohydrate, which provided the same energy intake.

The identification by the subject of his/her formula by its flavor which could affect the double-blind characteristic of the study was prevented by adding to the formulas of Diets A, B and C a common fluid shake. To avoid errors in energy intake, this fruit shake, by itself, provided the same energy intake. The fruit for the shake was changed almost daily, and was chosen from Table V.

Table V

Food	Composition x 100 g	Energy (Calories)
Fruits	Protein	
Pineapple	0.4	52
Pondapple	0.4	52
Papaya	0.5	32
Watermelon	0.5	22

To avoid a nitrogen over-intake per g/kg/day, which could affect the nitrogen balance, the subject's protein requirement was based on his/her ideal weight. A daily vitamin-mineral supplement according to Example 4 was given to all subjects.

Determining weight

The subject's weight (in kg) was determined, in the early morning after subject's urination and evacuation, and before breakfast. The result was rounded off to the nearest 0.100 kg (range 50 g).

Determining Ideal Weight

The subject's ideal weight (in kg) was obtained by substracting factor 100 from the subject's height (in cm), then multiplying the result by either factor 0.9 (male) or 0.8 (female), in accordance with subject's sex. The result was rounded off to the nearest 0.500 kg (range 250 g). The following formula was applied:
male's ideal weight = [(Height - 100) x 0.9] kg
female's ideal weight = [(Height - 100) x 0.8] kg

Determining Nitrogen Balance

To determine the subject's nitrogen balance, the following formula was used:

$$B = I - (U + F + S)$$

where
B = N balance;
I = N Intake;
U = N loss in urine;
F = N loss in feces; and
S = N dermal losses.

The nitrogen balance represents the difference between N intake (I) , and N output (U + F + S), the difference being either positive (N retention), as in active growth, negative (N loss), or zero (N equilibrium).

Determining Nitrogen Intake

To determine the subject's nitrogen intake (I), the following formula is used:
Diet protein amount = Dietary nitrogen x 6.25 where use of factor 6.25, implies that the average protein contains 16% nitrogen.

Determining Nitrogen Loss

The urine (U) and feces (F), of each subject are collected throughout each 24 hour day of each consecutive 28 day period, to determine the nitrogen loss by micro-Kjeldahl techniques.
To determine the subject's nitrogen dermal and minor route losses (S), a constant factor was used:

(S) = 5 mg x subject weight (kg) x day

Determining Nitrogen Balance

This calculation was made by taking into consideration the subject's real weight. To avoid any misinterpretation in the subject's daily nitrogen balance, which is not usually constant, the subject's diet nitrogen intake (I) per period, and the diet nitrogen output (U + F + S) per period, were obtained by adding up the subject daily nitrogen intake and output amounts, during the diet period.
The subject's nitrogen balance was obtained by the difference between the dietary nitrogen intake (I) per period, and the dietary nitrogen output (U + F + S) per period.

Determining Mean Nitrogen Loss

The mean of each subject's nitrogen loss, per period, was obtained by adding up each subject nitrogen loss amount during a diet period, and dividing the result by the total number of subjects.

Determining Mean Protein Loss

The mean protein loss per each subject per period, is obtained by multiplying the mean nitrogen loss per period by factor 6.25. All calculations were in accordance with the following formula:

PROTEIN = (N g) x 6.25

where it is assumed that the N content of the mixed proteins of the body is 16%. Thus 1 g of N excreted represent a loss from the body of 6.25 g of mixed proteins.

Determining Mean Tissue Loss

The mean tissue loss per subject per period, is obtained by multiplying the mean protein loss per period by factor 5. All calculations are in accordance with the following formula:

LEAN TISSUE = (N g) x 6.25 x 5

To illustrate: the N content of the mixed proteins of the body is 16%. Thus 1 g of N excreted represents a loss from the body of 6.25 g of mixed proteins. Intracellular protein exists in app roximately a 20 to 25% aqueous solution in the lean tissue of the body (the fat-free, connective tissue-free, and bone-free "wet" tissue).

Assuming that 1 g protein is associated with 5 g of hydrated lean tissue, then 1 g of excreted nitrogen represents a loss of 1 x 6.25 x 5 = 31.25 g of lean tissue.

Determining Mean Nitrogen Loss Per Kilo Per Period

The subjects' mean nitrogen loss per subject per kg per period, is obtained by dividing the subjects' mean nitrogen loss per period by the mean ideal weight.

Determining Range of Mean Nitrogen Loss Per Kilo Per Period

The subjects' range of mean nitrogen loss per subject per kg per period, is obtained by calculating the difference between the highest and lowest subject's nitrogen loss per period.

RESULT OF THE STUDY

GROUP "1" NITROGEN BALANCE RESULTS BY DIET			
Diet	A	B	C
Group 1	equilibrium	negative	negative

The following are the nitrogen balance results obtained from Group "1" comprised of twenty-two subjects, with a mean ideal weight of 55 kg, during each 28 day diet period:

DURING DIET " A"

Period: 28 days Subjects: 22

NITROGEN BALANCE per subject per period: EQUILIBRIUM

(found in all twenty two subjects)

Mean Nitrogen Loss per subject per period: NONE

Mean Protein Loss per subject per period: NONE

Mean Lean Tissue Loss per subject per period: NONE

DURING DIET "B"

Period 28 days Subjects: 22

NITROGEN BALANCE per subject per period: NEGATIVE

(found in all twenty two subjects)

Mean Nitrogen Loss per subject per period: 28.56 g

Mean Nitrogen Loss per kg per period: 519 mg

Mean Protein Loss per subject per period: 178.50 g

Mean Lean Tissue Loss per subject per period: 892.50 g

DURING DIET "C"

Period 28 days Subjects: 22

NITROGEN BALANCE per subject per period: NEGATIVE

(found in all twenty two subjects)

Mean Nitrogen Loss per subject per period: 32.78 g

Mean Nitrogen Loss per kg per period: 596 mg

Mean Protein Loss per subject per period: 204.87 g

Mean Lean Tissue Loss per subject per period: 1,024.37 g

GROUP "2" NITROGEN BALANCE BY DIET			
Diet	B	C	A
Group 2	negative	negative	equilibrium

The following are the nitrogen balance results obtained from Group "2" comprises of twenty-two subjects, with mean ideal weight of 53.5 kg, during each 28 day diet period:

DURING DIET "B"

Period: 28 days Subjects: 22

NITROGEN BALANCE per subject per period: NEGATIVE

(Found in all twenty two subjects)

Mean Nitrogen Loss per subject per period: 26.51 g

Mean Nitrogen Loss per kg per period: 495 mg

Mean Protein Loss per subject per period: 165.68 g

Mean Lean Tissue Loss per subject per period: 828.43 g

DURING DIET "C"

Period: 28 days Subjects: 22

NITROGEN BALANCE per subject per period: NEGATIVE

(Found in all twenty two subjects)

Mean Nitrogen Loss per subject per period: 30.47 g

Mean Nitrogen Loss per kg per period: 569 mg

Mean Protein Loss per subject per period: 190.43 g

Mean Lean Tissue Loss per subject per period: 952.18 g

DURING DIET "A"

Period: 28 days Subjects: 22

NITROGEN BALANCE per subject per period: EQUILIBRIUM

(Found in all twenty two subjects)

Mean Nitrogen Loss per subject per period: NONE

Mean Protein Loss per subject per period: NONE

Mean Lean Tissue Loss per subject per period: NONE

GROUP "3" NITROGEN BALANCE BY DIET			
Diet	C	A	B
Group 3	negative	equilibrium	negative

The following are the nitrogen balance results obtained from Group "3" comprises of twenty-two subjects, with a mean ideal weight of 53 kg, during each 28 day diet period:

DURING DIET "C"

Period: 28 days Subjects: 22

NITROGEN BALANCE per subject per period: NEGATIVE

(Found in all twenty two subjects)

Mean Nitrogen Loss per subject period: 30.43 g

Mean Nitrogen Loss per kg per period: 574 mg

Mean Protein Loss per subject per period: 190.18 g

Mean Lean Tissue Loss per subject per period: 950.93 g

DURING DIET "A"

Period: 28 days Subjects: 22

NITROGEN BALANCE per subject per period: EQUILIBRIUM

(Found in all twenty two subjects)

Mean Nitrogen Loss per subject per period: NONE

Mean Protein Loss per subject per period: NONE

Mean Lean Tissue Loss per subject per period: NONE

DURING DIET "B"

Period: 28 days Subjects: 22

NITROGEN BALANCE per subject per period: NEGATIVE

(Found in all twenty two subjects)

Mean Nitrogen Loss per subject per period: 26.57 g

Mean Nitrogen Loss per kg per period: 501 mg

Mean Protein Loss per subject per period: 166.06 g

Mean Lean Tissue Loss per subject per period: 830.31 g

NITROGEN BALANCE BY GROUP AND DIET			
Diet	A	B	C
Group 1	equilibrium	negative	negative
Group 2	equilibrium	negative	negative
Group 3	equilibrium	negative	negative

The following are the nitrogen balance results obtained from the sixty-six subjects belonging to Groups 1, 2, and 3, with a mean ideal weight of 54 kg during each consecutives 28 days diet period:

DURING DIET "A"

Period: 28 days	Subjects: 66
NITROGEN BALANCE per subject per period:	EQUILIBRIUM
(Found in all sixty-six subjects)	
Mean Nitrogen Loss per subject per period:	NONE
Mean Protein Loss per subject per period:	NONE
Mean Lean Tissue Loss per subject per period:	NONE

DURING DIET "B"

Period: 28 days	Subjects: 66
NITROGEN BALANCE per subject per period:	NEGATIVE
(Found in all sixty-six subjects)	
Mean Nitrogen Loss per subject per period:	27.21 g
Mean Nitrogen Loss per kg per period:	504 mg
Range of Mean Nitrogen Loss per kg per period:	27 mg
Mean Protein Loss per subject per period:	170.06 g
Mean Lean Tissue Loss per subject per period:	850.31 g

DURING DIET "C"

Period: 28 days	Subject: 66
NITROGEN BALANCE per subject per period:	NEGATIVE
(Found in all sixty-six subjects)	
Mean Nitrogen Loss per subject per period:	31.22 g
Mean Nitrogen Loss per kg per period:	578 mg
Range of Mean Nitrogen Loss per kg per period:	28 mg
Mean Protein Loss per subject per period:	195.12 g
Mean Lean Tissue Loss per subject per period:	975.62 g

The sixty-six subjects have shown:

(a) the highest net nitrogen utilization (NNU) when receiving the formula of Table I, during Diet A periods, by achieving "equilibrium" in their nitrogen balances;
(b) a lower net nitrogen utilization (NNU) when receiving hen whole egg amino acids formula, during Diet B periods, by obtaining negative nitrogen balances, with a mean nitrogen loss per subject equivalent to 504 mg/kg/period, which was 28% less net nitrogen utilization (NNU) than when receiving the formula of Table I during Diet A; and
(c) the lowest net nitrogen utilization (NNU) when receiving dried hen whole egg, during Diet C periods; by obtaining negative nitrogen balances, with a mean nitrogen loss per subject equivalent to 578 mg/kg/period, which was 32% less apparent protein digestibility than when receiving the formula of Table I during Diet A periods.

The hen whole egg protein has been considered to be the protein food with the highest net nitrogen utilization (NNU). The formula of Table I has shown the highest net nitrogen utilization (NNU) by all sixty-six subjects, than both hen whole egg and hen whole egg amino acid formula. It can be concluded that the formula of Table I has a higher apparent protein digestibility than hen whole egg protein.

Claims

1. A nutritional composition comprising a combination of the following:
(a) isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, and valine in amounts relative to one another which will provide a Net Nitrogen Utilization (NNU) of at least 80%;
(b) a carbohydrate selected from the group consisting of sucrose, maltose and sorbitol, and a highly polyunsaturated vegetable fat selected from the group consisting of safflower oil, sunflower oil and corn oil; and
(c) for each gram of amino acid, an amount of vitamins, which is equivalent to the following:

Vitamin A	60.0 - 109.0 mcg
Vitamin D	37.0 - 63.0 mcg
Alpha-tocopherol	0.78 - 1.30 mg
Vitamin K	2.0 - 4.0 mcg
Vitamin B_1	10.0 - 20.0 mcg
Vitamin B_2	27.0 - 48.0 mcg
Nicotinamide	0.13 - 0.23 mg
Pantothenic Acid	0.18 - 0.30 mcg
Vitamin B_6	13.0 - 23.0 mcg
Biotin	0.43 - 0.73 mcg
Folic Acid	3.5 - 6.5 mcg
Vitamin B_{12}	35.0 - 65.0 ng
Vitamin C	3.5 - 6.5 mg.

2. A nutritional composition as defined in Claim 2, which includes the following minerals in weight percent:

Sodium	7.64 - 13.53
Potassium	24.12 - 40.58
Magnesium	1.47 - 2.94
Calcium	15.88 - 26.47
Manganese	0.00061 - 0.00205
Iron	0.021 - 0.0588
Cobalt	0.00058 - 0.0011
Zinc	0.020 - 0.038
Nickel	0.094 - 0.164
Chromium	0.00044 - 0.0014
Molybdenum	0.029 - 0.050
Vanadium	0.00041 - 0.0029
Phosphorous	0.00020 - 0.00038
Chloride	6.471 - 20.590
Fluoride	17.649 - 29.415
Iodine	0.007 - 0.012
Selenium	0.0023 - 0.0046
Bromine	0.0011 - 0.0026
Boron	0.041 - 0.076
Silicon	0.0023 - 0.0047

3. A nutritional composition as defined in Claim 1 wherein in the Net Nitrogen Utilization is at least .90%.

4. A nutritional composition as defined in Claim 1 which comprises in grams per 10 grams of composition:
   (a) from 1.289 to 1.530 isoleucine;
   (b) from 1.827 to 2.295 leucine;
   (c) from 0.232 to 0.778 lysine;
   (d) from 0.936 to 1.314 methionine;
   (e) from 1.028 to 1.287 phenylalanine;
   (f) from 0.238 to 0.467 threonine;
   (g) from 1.260 to 1.900 tryptophan; and
   (h) from 1.260 to 2.359 valine.

5. A nutritional composition as defined in Claim 3 wherein the carbohydrate and highly polyunsaturated vegetable fat comprise from 12Kcal to 60Kcal per gram of amino acids.

6. A nutritional composition comprising a combination of the following essential amino acids:
   isoleucine;
   leucine;
   lysine;
   methionine;
   phenylalanine;
   threonine;
   tryptophan; and
   valine,
   in amounts relative to one another which will provide a net nitrogen utilization of at least 80%.

7. A nutritional composition as defined in Claim 5, which includes vitamins.

8. A nutritional composition as defined in Claim 6, which includes minerals.

9. A nutritional composition as defined in Claim 7, which also includes a source of carbohydrate and polyunsaturated vegetable fat.

10. A nutritional composition which comprises in grams per 10 grams of composition:
    (a) from 1.289 to 1.530 isoleucine;

(b) from 1.827 to 2.295 leucine;
(c) from 0.232 to 0.778 lysine;
(d) from 0.936 to 1.314 methionine;
(e) from 1.028 to 1.287 phenylalanine;
(f) from 0.238 to 0.467 threonine;
(g) from 1.260 to 1.900 tryptophan; and
(h) from 1.260 to 2.359 valine.

11. A nutritional composition as defined in Claim 10, which also includes vitamins.

12. A nutritional composition as defined in Claim 10, which also includes a source of carbohydrate and a polyunsaturated vegetable fat.

13. A nutritional composition which comprises:
(a) from 70-95 wt. % of a protein-free carbohydrate selected from the group consisting of maltose, sucrose and sorbitol;
(b) from 5-30 wt. % of a protein-free highly unsaturated vegetable fat selected from the group consisting of safflower oil, sunflower oil and corn oil.

14. A vitamin composition which comprises the following vitamins in weight percent:

Vitamin A	0.036 - 0.063
Vitamin D	0.000021 - 0.00003
Alpha-tocopherol	0.229 - 0.382
Vitamin K	0.229 - 0.382
Vitamin B_1	0.0011 - 0.0023
Vitamin B_2	0.0058 - 0.0117
Nicotinamide	0.015 - 0.028
Pantothenic acid	0.076 - 0.135
Vitamin B_6	0.105 - 0.176
Biotin	0.0076 - 0.013
Folic Acid	0.00025 - 0.0006
Vitamin B_{12}	0.0020 - 0.0038
Vitamin C	0.000020 - 0.00003
	2.05 - 3.82